K021373
p.1/2

JUN 27 2002

Special 510(k): Device Modification Summary

Submitter:

Harlan Van Matre, Manager of Quality Assurance / Regulatory Affairs
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
Fax: (414) 354-4760
Phone: (414) 354-1600
Contact: Harlan Van Matre (see above)

Trade Name: H12+
Common Name: Holter Recorder
Classification Name: Medical Magnetic Tape Recorder (based on classification for original device.) (Per 21 CFR 870.2800)

Legally marketed devices to which S. E. is claimed

The H12+ Holter Recorder is a modification of a legally marketed Mortara predicate device.

- Mortara PR4 Holter Recorder (K9110977)

Note: For commercial reasons, Mortara changed the proprietary name from PR 4 to H-12 in 1995 and has continued to distribute the device under the H-12 name. The "new" H12+ is the latest evolution of this Mortara predicate device.

Description:

The Mortara H12+ is a Holter Recorder designed to be used in conjunction with the Mortara H-Scribe Holter Analysis system. The H12+ acquires, digitizes and stores data to be analyzed by the H-Scribe Holter System. The H12+ utilizes a 10-lead electrode hookup and placement to provide the H-Scribe system with three channels of full disclosure for Holter analysis. The cardiac data provided by H-Scribe is used by trained medical personnel to assist in the diagnosis of patients with various rhythm patterns.

The H12+ Holter recorder stores 12 leads continuously for a 24-hour period. A keypad is available to set up system configuration, to enter patient's ID, to check lead quality during hook-up, and to start the recording. During the recording, the keypad can be used to enter event markers.

H12+ has a LCD screen to allow ECG display during the hook-up, lead quality check, system configuration and various messages for the hook-up technician.

H12+ uses one AA battery, and a removable memory card for data storage.

Intended use:

The H12+ Holter recorder is intended to acquire, record and store up to 24 hours of ECG data of patients that have been connected to the Mortara H12+ recorder and are undergoing Holter monitoring. The H12+ performs no cardiac analysis by itself and is intended to be used with the H-Scribe Holter analysis system (K004017). ECG data prerecorded by the H12+ is acquired and analyzed by the H-Scribe. In turn the cardiac data and analysis provided by H-Scribe Holter system will be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

Indications for use:

The H12+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of 24 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis.

Holter analysis is appropriate for the indications below:

- Evaluation of adult patients with symptoms suggesting arrhythmia or myocardial ischemia.
- Evaluation of adult patients for ST segment changes
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of a patients response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Clinical and epidemiological research studies
- Infant patient evaluation is limited to QRS detection only

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

Mortara Instrument, Inc.
c/o Mr. Harlan L. Van Matre
Manager of Quality Assurance and Regulatory Affairs
7865 North 86th Street
Milwaukee, WI 53224-3431

Re: K021373
Trade Name: Mortara Holter Recorder H12+
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: May 29, 2002
Received: May 31, 2002

Dear Mr. Van Matre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respirator Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012373

Device Name: **Mortara H12+ Holter Recorder**

The H12+ Holter recorder is intended to acquire, record and store ECG data of patients that have been connected to the Mortara H12+ recorder and are undergoing Holter monitoring. The H12+ acquires, digitizes and stores data to be analyzed by the H-Scribe Holter system. The H12+ performs no cardiac analysis by itself and is intended to be used with the H-Scribe Holter analysis system (K004017). ECG data prerecorded by the H12+ is acquired and analyzed by the H-Scribe. In turn the cardiac data and analysis provided by H-Scribe Holter system will be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

The H12+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of 24 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. Holter analysis is appropriate for the indications below:

- Evaluation of adult patients with symptoms suggesting arrhythmia or myocardial ischemia.
- Evaluation of adult patients for ST segment changes
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of a patients response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Clinical and epidemiological research studies
- Infant patient evaluation is limited to QRS detection only

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

Prescription Use_____ OR **Over-The-Counter Use**_____
(Per 21CFR801.109)

510(k) Number K012373

(Optional Format 1-2-96)